K110429

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Section III -510(k) Summary of Safety and Effectiveness

Submitter:

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Device Name:

- Trade Name – ProSim 4
- Common Name –Vital Signs Simulator
- Classification Name - Monitor,Cardiac /System, Measurement, Blood-Pressure, Non-Invasive per 21 CFR 870.2300/870.1130
- Product Codes –DRT, DXN

Devices for Which Substantial Equivalence is Claimed:

- MedSim300B _Submitted as MedSim300 under 510(k) K935817
- Cufflink

Device Description:

Principles of Operation

Fluke Biomedical's ProSim 4 (hereafter referred to as the ProSim) provides a basis to train, evaluate, and perform preventive maintenance for virtually all patient monitors found in the healthcare industry. This is accomplished with multiple physiological simulations for ECG electrical signals, respiration electrical signals, invasive blood pressure (IBP) electrical signals and non-invasive blood pressure (NIBP) pressure pulses. The ProSim is a lightweight, battery powered unit that is portable enough to test a patient monitor anywhere the monitor is being used.

Technological Characteristics

ProSim vital signs simulator consists of the following components:

1) Printed Circuit Board Assemblies using surface mount components and firmware loaded in embedded processors.
2) Plastic injection molded case parts.
3) Stepper Motor and piston pump for pneumatic simulation that makes reliable pressure pulses.
4) Liquid Crystal Touch Screen Display for user interface. User interface follows modern and ergonomic concepts.
5) Lithium Ion rechargeable battery for portable operation, giving user flexibility and portability.

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Intended Use of the Device:

The intended us of ProSim 4 is to test and verify the basic operation of patient monitoring devices or systems used to monitor various physiological parameters of a patient, including ECG, Respiration, Invasive blood pressure and Non-invasive blood pressure.

The intended user is a trained biomedical equipment technician who is performing periodic preventative maintenance checks on patient monitors in service. Users can be associated with hospitals, clinics, original equipment manufacturers and independent service companies that repair and service medical equipment. The end user is a technically trained individual, specializing in medical instrumentation technology.

The ProSim is intended to be used in the laboratory environment and is not intended for use on patients, or to test devices while connected to patients. This product line is not intended to be used to calibrate medical equipment.

ProSim is intended for over-the counter use.

Summary of Technological Characteristics:

The *ProSim 4* is substantially equivalent to one other legally marketed device in the United States. The *ProSim* functions in a manner similar to and is intended for the same use as the *MedSim300B and Cufflink* manufactured by Fluke Biomedical.

The ProSim 4 is similar to the *MedSim300B and Cufflink* in that it is a cordless battery-operated device, uses LCD display, and allows user to simulate physiological parameters to verify the operation of patient monitors. The *ProSim* differs from the *MedSim300B and Cufflink* in that the *ProSim* combines the features of each of these devices into one device and is touch screen operated.

Features	ProSim 4	MedSim 300B (K935817)	Cufflink (K942546)	Difference
Intended Use	The intended use of ProSim 4 is to test and verify the basic operation of patient monitoring devices or systems used to monitor various physiological parameters of a patient, including ECG, Respiration, Invasive blood pressure and Non-invasive blood pressure. The intended user is a trained biomedical equipment technician who is performing periodic preventative maintenance checks on patient monitors in service. Users can be associated with Hospitals, clinics, original equipment manufacturers or independent service companies that repair and service medical	To test operation of patient monitors by simulating physiological parameters, including: ECG, respiration, blood pressure, temperature and cardiac output.	To test operation of Non-Invasive Blood Pressure (automated Sphygmomanometers simulator).	None

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	equipment. The end user is a technically trained individual, specializing in medical instrumentation technology. The ProSim product line is intended to be used in the laboratory environment and is not intended for use on patients, or to test devices while connected to patients. This product line is not intended to be used to calibrate medical equipment and not intended for over the counter use.			
Construction	Plastic case.	Aluminum case.	Aluminum case.	Lighter more compact plastic casing.
Size	ProSim 4: 7.1 L x 3.7 W x 2.2 H inches.	10 L x 7 W x 3 H inches.	15 L x 12.5 W x 5 H inches.	Combination instrument smaller than sum of predicate devices.
Weight	ProSim 4: 1.9 lbs.	3.55 lbs.	15 lbs.	Lighter.
Display	¼ VGA graphic LCD Touch Color Display.	2 by 24 character LCD.	8 by 20 character alphanumeric display & 64 by 240 graphical display.	More display, Touch Screen and Color.
Function Key	ProSim 4: Touchscreen.	Soft.	Soft.	ProSim 4: Touchscreen.
ECG leads	10 binding posts; compatible w/ disposable snaps, 3.2 mm or 4.0 mm electrodes, and banana plugs (with or without adapter).	10 binding posts; compatible w/ disposable snaps, 3.2 mm or 4.0 mm electrodes, and banana plugs.	N/A	None.
IBP Channels	Independent BP channels w/ sensitivity control (5 or 40 uV/V/mmHg); cable interface w/ monitors. ProSim 4: 1 channel.	4 independent BP channels w/ sensitivity control (5 or 40 uV/V/mmHg); cable interface w/ monitors.	N/A	Number of channels reduced per market requirements and use.
Communications Port	USB.	RS232.	RS232.	Change from RS232 to USB data port with advancement in technology.

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Battery test	Multiple levels of battery life indication.	Limited low battery indication.	No battery.	Predicate devices only check at one level. ProSim checks battery status at multiple charge levels.
Power	Li-Ion rechargeable battery w/ low battery indicator; or battery eliminator (115VAC) transformer certified to CSA.	2 X 9V alkaline battery w/ low battery indicator; or battery eliminator (115VAC) transformer certified to CSA C22.2. 231 series M89).	No Battery- AC line powered only.	Longer operating life with modern battery technology.
Lead configuration	12 leads.	12 leads.	N/A	None.
Output impedances	500 to 2000ohms to RL.	500 to 2000ohms to RL.	N/A	None.
Amplitude accuracy	+/- 2% setting lead II.	+/- 5%, 2Hz @ 1.0 mV p-p SQ wave Lead II.	N/A	More accurate on newer devices due to market preferences and technology improvements.
NSR rates	ProSim 4: 30 to 320 BPM.	30 to 300 BPM.	N/A	Wider range due to market preferences.
NSR amplitudes	ProSim 4: 1mV	50 uV to 5.5mV.	N/A	ProSim 4: Limited amplitude for basic simulation.
Pediatric or Neonatal ECG	R Wave width reduced to 40 ms.	R Wave width reduced to 40 ms.	N/A	None.
Square and/or Pulse waves	ProSim 4: Pulse at 60ms / 2Hz.	Square at 2 Hz and 0.125 Hz.	N/A	ProSim 4: Provides what is required for a basic simulation.
Pacemaker	ProSim 4: 1 ms width, 3mV.	0.1 to 2.0 ms width, -700 to +700 mV	N/A	ProSim 4: Basic simulation for targeted market.
Cable connector	ECG leads, 10 binding postings.	ECG leads, 10 binding postings.	N/A	None.
Normal baseline impedances	500 to 2000 ohms ref. to RL.	500 to 2000 ohms ref. to RL.	N/A	None.
Lead selections	LA or LL.	I or II (LA or LL).	N/A	None.
Impedance variation	ProSim 4: 1.0 ohm	0 to 3 ohms.	N/A	ProSim 4: Basic simulation for targeted market.

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Respiration rates	ProSim 4: 10, 20, 30, 40, 50, 60, 70, 80, 90 & 100 brpm.	15, 20, 30, 40, 60, 120 brpm.	N/A	More Respiration rates due to market requirements and use.
Apnea	ProSim 4: Off & Continuous.	Off, Continuous, momentary, 12 & 32 s.	N/A	ProSim 4: Less apneas for basic simulation and target market.
Cable connector	ECG leads, binding posts.	ECG leads, binding posts.	N/A	None
I/O impedance	300 ohms.	300 ohms.	N/A	None.
Exciter range	2 to 16 V/DC to 5kHz.	2 to 16 V/DC to 4 kHz	N/A	Higher frequency range driven by market trend and technology.
Transducer Sensitivity	ProSim 4: 5 uV/V/mmHg	5 or 40 uV/V/mmHg.	N/A	ProSim 4: Fewer selections for basic simulation and target market.
Level accuracy	+/- (1% setting + 1mmHg).	+/- 1% full scale; +/- 1mmHg.	N/A	None.
Static pres. Selection	Manual.	Manual and automatic.	N/A	Limited selection mode per target market and use.
Dynamic BP selections	ProSim 4: Arterial and left ventricle.	Arterial, left and right ventricle, pulmonary artery, pulmonary wedge, Swan-Ganz.	N/A	ProSim 4: Fewer selections for basic simulation and target market.
Static BP selections	ProSim 4: 0, 80, 160 & 250 mmHg	-10, -5, 0, 20, 30, 40, 80, 100, 200, 250 & 300 mmHg.	N/A	ProSim 4: Fewer selections for basic simulation and target market.
Cable connector	DIN style.	DIN style.	N/A	None.
Manometer	0 to 400 mmHg	N/A	Max. 499.75 mmHg	Lower range following market requirements.
Leak Test	Source pressure, seal off, measure change in pressure over time.	N/A	Source pressure, seal off, measure change in pressure over time.	None.
Over Pressure Test	Increase pressure until device under tests vents to atmosphere.	N/A	Increase pressure until device under tests vents to atmosphere.	None.

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Simulation	ProSim 4: Systolic/Diastolic Adult – 60/30, 120/80, 150/100 & 200/150; Neonatal 35/15 & 70/40.	N/A	Systolic/Diastolic simulations. Adult 60/30 to 255/195.	ProSim 4: Fewer selections for basic simulation. Adult and Neonatal.
Synchronization to ECG	ProSim 4: Up to 150 BPM	N/A	30 to 240 BPM	ProSim 4: Limited for basic simulation.

Non-Clinical Test Data:

Laboratory studies have been conducted with a representative patient monitor to verify and validate the ProSim 4 will perform within its' published specifications.

- NPI-02042011-00001 ProSim 4 Bench test summary and results.

The *ProSim 4* software has been successfully validated to confirm the performance of the device.

Clinical Test Data:

Clinical testing has not been conducted on this product.

Conclusion:

Based upon the laboratory studies, similar technological/performance characteristics as compared to the predicate devices, and successful validation of the *ProSim 4* software, the performance of the *ProSim 4* is deemed to be substantially equivalent to the *MedSim300B and Cufflink.*

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Device Name:

- Trade Name –ProSim 6, ProSim 8
- Common Name –Vital Signs Simulator
- Classification Name - Monitor,Cardiac /System, Measurement, Blood-Pressure, Non-Invasive per 21 CFR 870.2300/870.1130
- Product Codes –DRT, DXN

Devices for Which Substantial Equivalence is Claimed:

- MedSim300B _Submitted as MedSim300 under 510(k) K935817
- Index 2MF SPO2 – Originally submitted and cleared under 510(k) K933519. Currently marketed as Index 2MF which was ruled as a general purpose device on Feb 11, 1998 (K974293)
- Cufflink

Device Description:

Principles of Operation

Fluke Biomedical's ProSim 6 and ProSim 8 (hereafter referred to as the ProSim) provides a basis to train, evaluate, and perform preventive maintenance for virtually all patient monitors found in the healthcare industry. This is accomplished with multiple physiological simulations for ECG electrical signals, respiration electrical signals, invasive blood pressure (IBP) electrical signals, non-invasive blood pressure (NIBP) pressure pulses, temperature electrical signal, cardiac output electrical signal, and pulse oximetry SPO2 optical simulated light attenuation. The ProSim is a lightweight, battery powered unit that is portable enough to test a patient monitor anywhere the monitor is being used.

Technological Characteristics

ProSim vital signs simulator consists of the following components:

1) Printed Circuit Board Assemblies using surface mount components and firmware loaded in embedded processors.
2) Plastic injection molded case parts.
3) Stepper Motor and piston pump for pneumatic simulation that makes reliable pressure pulses.
4) Liquid Crystal Display for user interface. User interface follows modern and ergonomic concepts.
5) Lithium Ion rechargeable battery for portable operation, giving user flexibility and portability.

Intended Use of the Device:

The intended us of ProSim 6 and ProSim 8 is to test and verify the basic operation of patient monitoring devices or systems used to monitor various physiological parameters of a patient, including ECG, Respiration, Invasive blood pressure, Non-invasive blood pressure, Temperature and Cardiac output. Additionally, the devices provide an optical signal to verify that the electronics within the pulse oximeter probe are functional.

The intended user is a trained biomedical equipment technician who is performing periodic preventative maintenance checks on patient monitors in service. Users can be associated with hospitals, clinics, original equipment manufacturers and independent service companies that repair and service medical equipment. The end user is a technically trained individual, specializing in medical instrumentation technology.

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The ProSim is intended to be used in the laboratory environment and is not intended for use on patients, or to test devices while connected to patients. This product line is not intended to be used to calibrate medical equipment.

ProSim is intended for over-the counter use.

Summary of Technological Characteristics:

The *ProSim* is substantially equivalent to one other legally marketed device in the United States. The *ProSim* functions in a manner similar to and is intended for the same use as the *MedSim300B, Index 2 and Cufflink* manufactured by Fluke Biomedical.

The ProSim is similar to the *MedSim300B, Index 2 and Cufflink* in that it is a cordless battery-operated device, uses LCD display, and allows user to simulate physiological parameters to verify the operation of patient monitors. The *ProSim* differs from the *MedSim300B, Index 2 and Cufflink* in that the *ProSim* combines the features of each of these devices into one device.

Features	ProSim 6 & ProSim 8	MedSim 300B (K935817)	Index 2 (K 933519)	Cufflink (K942546)	Difference
Intended Use	The intended use of ProSim 6 and ProSim 8 is to test and verify the basic operation of patient monitoring devices or systems used to monitor various physiological parameters of a patient, including ECG, Respiration, Invasive blood pressure, Non-invasive blood pressure, Temperature, Cardiac output and SpO2. The intended user is a trained biomedical equipment technician who is performing periodic preventative maintenance checks on patient monitors in service. Users can be associated with Hospitals, clinics, original equipment manufacturers or independent service companies that repair and service medical equipment. The end user is a technically trained individual, specializing in	To test operation of patient monitors by simulating physiological parameters, including: ECG, respiration, blood pressure, temperature and cardiac output.	To test operation of Pulse Oximeters by simulating the visible and infrared light absorption.	To test operation of Non-Invasive Blood Pressure (automated Sphygmomanometers) simulator).	Additional functions of noninvasive blood pressure and pulse oximetry simulation

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	medical instrumentation technology. The ProSim product line is intended to be used in the laboratory environment and is not intended for use on patients, or to test devices while connected to patients. This product line is not intended to be used to calibrate medical equipment and not intended for over the counter use.				
Construction	Plastic case.	Aluminum case.	Plastic case.	Aluminum case.	Lighter more compact plastic casing.
Size	5.7 L x 11.9 W x 3.4 H inches.	10 L x 7 W x 3 H inches.	10 L x 10.5 W x 4 H inches.	15 L x 12.5 W x 5 H inches.	Combination instrument smaller than sum of predicate devices.
Weight	4.1 lbs.	3.55 lbs.	4 lbs.	15 lbs.	Lighter.
Display	¼ VGA graphic LCD Color Display.	2 by 24 character LCD.	2 by 24 character LCD.	8 by 20 character alphanumeric display & 64 by 240 graphical display.	More display, Color.
Function Key	Soft.	Soft.	Soft.	Soft.	None.
ECG leads	10 binding posts; compatible w/ disposable snaps, 3.2 mm or 4.0 mm electrodes, and banana plugs (with or without adapter).	10 binding posts; compatible w/ disposable snaps, 3.2 mm or 4.0 mm electrodes, and banana plugs.	N/A	N/A	None.
High level ECG	BNC jack for 0.5V/mV output into 50 Ohm impedance.	¼" standard phone jack w/ lead II waveform at .2V/mV of ECG lead II signal. Use w/ analog input, high level, central station monitors or recorders.	N/A	N/A	Output to oscilloscope via BNC is preferred by customers.
IBP Channels	Independent BP channels w/ sensitivity control (5 or 40 uV/V/mmHg); cable interface w/ monitors. 2 channels.	4 independent BP channels w/ sensitivity control (5 or 40 uV/V/mmHg); cable interface w/ monitors.	N/A	N/A	Number of channels reduced per market requirements and use.
Respiration	Baseline Impedance	Baseline	N/A	N/A	None.

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	(500 – 2000) control; lead select control.	Impedance (500 – 2000) control; lead select control.			
Temperature	Yes, fixed temp. probe select control (400 or 700 YSI) series probes.	Yes, fixed or variable temp. probe select control (400 or 700 YSI) series probes.	N/A	N/A	None.
Cardiac output	Yes, cable connect w/ monitor.	Yes, cable connect w/ monitor.	N/A	N/A	None.
Communications Port	USB.	RS232.	RS232.	RS232.	Change from RS232 to USB data port with advancement in technology.
Battery test	Multiple levels of battery life indication.	Limited low battery indication.	Limited low battery indication.	No battery.	Predicate devices only check at one level. ProSim checks battery status at multiple charge levels.
Power	Li-Ion rechargeable battery w/ low battery indicator; or battery eliminator (115VAC) transformer certified to CSA.	2 X 9V alkaline battery w/ low battery indicator; or battery eliminator (115VAC) transformer certified to CSA C22.2. 231 series M89).	Rechargeable Lead Acid battery.	No Battery- AC line powered only.	Longer operating life with modern battery technology.
ECG					
Lead configuration	12 leads.	12 leads.	N/A	N/A	None.
Output impedances	500 to 2000ohms to RL.	500 to 2000ohms to RL.	N/A	N/A	None.
Amplitude accuracy	+/- 2% setting lead II.	+/- 5%, 2Hz @ 1.0 mV p-p SQ wave Lead II.	N/A	N/A	More accurate on newer devices due to market preferences and technology improvements.
NSR rates	30 to 360 BPM.	30 to 300 BPM.	N/A	N/A	Wider range due to market preferences.
NSR amplitudes	50 uV to 5.0mV.	50 uV to 5.5mV.	N/A	N/A	None.
ST Segments	-0.8 to + 0.8 mV.	-0.8 to + 0.8 mV.	N/A	N/A	None.
Axis deviation	Intermediate, horizontal and vertical.	Intermediate, horizontal and vertical.	N/A	N/A	None.

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Pediatric or Neonatal ECG	R Wave width reduced to 40 ms.	R Wave width reduced to 40 ms.	N/A	N/A	None.
Performance Test					
Square and/or Pulse waves	Square at 2.5, 2 & 0.125 Hz. Pulse at 60ms / 60 and 30 BPM	Square at 2 Hz and 0.125 Hz.	N/A	N/A	More choices.
Sine waves	0.05 to 150 Hz.	0.05 to 100 Hz.	N/A	N/A	More choices.
Triangle wave	0.125, 2 and 2.5 Hz.	2 Hz.	N/A	N/A	More choices.
R Wave detector	Yes.	Yes.	N/A		None
QRS Detection and Tall T-wave rejection.	Yes	No	N/A	N/A	None
Pacemaker	0.1 to 2.0 ms width, -700 to +700 mV	0.1 to 2.0 ms width, -700 to +700 mV	N/A	N/A	None
Cable connector	ECG leads, 10 binding postings.	ECG leads, 10 binding postings.	N/A	N/A	None.
Respiration					
Normal baseline impedances	500 to 2000 ohms ref. to RL.	500 to 2000 ohms ref. to RL.	N/A	N/A	None.
Lead selections	LA or LL.	I or II (LA or LL).	N/A	N/A	None.
Impedance variation	0 to 5 ohms.	0 to 3 ohms.	N/A	N/A	Expanded capability to meet new market requirements.
Respiration rates	15 to 120 brpm in incremental steps.	15, 20, 30, 40, 60, 120 brpm.	N/A	N/A	More Respiration rates due to market requirements and use.
Apnea	Off, Continuous, momentary, 12, 22 & 32 s.	Off, Continuous, momentary, 12 & 32 s.	N/A	N/A	Additional apneas.
Cable connector	ECG leads, binding posts.	ECG leads, binding posts.	N/A	N/A	None
Cardiac Output					
Catheter size	Fixed, 7F injective vol. 10 cc.	Fixed, 7F injective vol. 10 cc.	N/A	N/A	None.
Blood temperatures	36C to 38C in incremental steps.	36C to 38C and user programmable.	N/A	N/A	User programmable not included due to market requirements and use.
Injective temp	Chilled (0C) or 24 C.	Chilled (2C).	N/A	N/A	More selections per market requirements.

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Fixed blood flow rate	2.5, 5, 10 L/min.	3, 5, 7 L/min.	N/A	N/A	Different selections per market requirements.
Curves	Normal, faulty and L/R shunt.	Normal, interrupt, slow, L/R shunt.	N/A	N/A	None.
Output trend	No.	1 normal, 2 defective.	N/A	N/A	Not included due to market requirements and use.
Bath/Injective resistance	Continuously variable, 3 pin standard.	Continuously variable, 3 pin standard.	N/A	N/A	None.
Cable connector	Blood Temp - American Edward, 3 pin standard; Injective Temp - American Edward, 4 pin standard.	Blood Temp - American Edward, 3 pin standard; Injective Temp - American Edward, 4 pin standard.	N/A	N/A	None
Invasive Blood Pressure					
I/O impedance	300 ohms.	300 ohms.	N/A	N/A	None.
Exciter range	2 to 16 V/DC to 5kHz.	2 to 16 V/DC to 4 kHz	N/A	N/A	Higher frequency range driven by market trend and technology.
Transducer Sensitivity	5 or 40 uV/V/mmHg.	5 or 40 uV/V/mmHg.	N/A	N/A	None.
Level accuracy	+/- (1% setting + 1mmHg).	+/- 1% full scale; +/- 1mmHg.	N/A	N/A	None.
Static pres. Selection	Manual.	Manual and automatic.	N/A	N/A	Limited selection mode per target market and use.
Dynamic BP selections	Arterial, radial artery, left and right ventricle, pulmonary artery, pulmonary wedge, right atrium, left atrium and Swan-Ganz.	Arterial, left and right ventricle, pulmonary artery, pulmonary wedge, Swan-Ganz.	N/A	N/A	More selections.
Static BP selections	-10 to 300 mmHg in incremental steps.	-10, -5, 0, 20, 30, 40, 80, 100, 200, 250 & 300 mmHg.	N/A	N/A	More selections.

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Cable connector	DIN style.	DIN style.	N/A	N/A	None.
Temperature					
Temperature	30C to 42C in incremental steps.	0, 24, 37 and 40C.	N/A	N/A	Different selections per market requirements.
Probe compatibility	Series 400 and 700.	Series 400 and 700.	N/A	N/A	None.
Cable connector	DIN Style.	DIN Style.	N/A	N/A	None.
Oximeter SPO2 optical emitter and detector					
SpO2 R-Curve selection	Select R-Curve from menu of choices.	N/A	Select R-Curve from menu of choices.	N/A	None.
SpO2 Pulse rate selection	Select BPM rate in 1 BPM increments.	N/A	Select BPM rate in 1 BPM increments.	N/A	None.
SpO2 accuracy	Select 30% to 100% in 1% increments With oximeter manufacturer's R-curve Saturation within UUT specific range ±(1 count + specified accuracy of the UUT) Saturation outside UUT specific range monotonic with unspecified accuracy With Fluke Biomedical R-curves 91 to 100 % ±(3 counts + specified accuracy of the UUT) 81 to 90 % ±(5 counts + specified accuracy of the UUT) 71 to 80 % ±(7 counts + specified accuracy of the UUT) Below 70 % monotonic with unspecified accuracy	N/A	Select 50% to 100% in 1% increments-accuracy: 75%to 100% +- 1% plus the accuracy of the pulse oximeter under test. 50%-75%, +- 2% plus the accuracy of the oximeter under test. Under 50%, unspecified.	N/A	More selections per market requirements.
SpO2 Test	Optical.	N/A	Probe electrical simulation test.	N/A	Electrical simulation of the finger probe is not needed with modern oximeters.
SpO2 test features	Transmission of light selected through selection of finger type: light finger, thick dark finger or neonate.	N/A	Transmission Light Control (TLC) feature in Index 2 is a quantity that simulates different light	N/A	Better user interface and understanding of transmission with ProSim selection of light transmission

			attenuation.		levels.
Magnetic Holder	Yes	N/A	No	N/A	Includes tested magnetic holder for SPO2 module.
Non-Invasive Blood Pressure					
Manometer	0 to 400 mmHg	N/A	N/A	Max. 499.75 mmHg	Lower range following market requirements.
Leak Test	Source pressure, seal off, measure change in pressure over time.	N/A	N/A	Source pressure, seal off, measure change in pressure over time.	None.
Over Pressure Test	Increase pressure until device under tests vents to atmosphere.	N/A	N/A	Increase pressure until device under tests vents to atmosphere.	None.
Simulation	Systolic/Diastolic Adult 60/30 to 255/195; Neonatal 35/15 to 255/195.	N/A	N/A	Systolic/Diastolic simulations. Adult 60/30 to 255/195.	Adult and Neonatal available.
Arrhythmias	Premature atrial contraction, Premature ventricular contraction, Atrial fibrillation, Missed Beat.	N/A	N/A	Premature atrial contraction, Premature ventricular contraction, Atrial fibrillation, Missed Beat, aberrant Sinus conduction.	No aberrant Sinus conduction. Not needed per market use.
Synchronization to ECG	30 to 240 BPM	N/A	N/A	30 to 240 BPM	None.

Non-Clinical Test Data:

Laboratory studies have been conducted with a representative patient monitor to verify and validate the ProSim 6 and ProSim 8 will perform within its' published specifications.

- NPI-01282011-00007 ProSim 6_8 Bench test summary and results

The ProSim 6 and ProSim 8 software has been successfully validated to confirm the performance of the device.

Clinical Test Data:

Clinical testing has not been conducted on this product.

Conclusion:

Based upon the laboratory studies, similar technological/performance characteristics as compared to the predicate devices, and successful validation of the ProSim 6 and ProSim 8 software, the performance of the ProSim 6 and ProSim 8 is deemed to be substantially equivalent to the *MedSim300B, Index 2 and Cufflink.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Fluke Biomedical
c/o Mr. John Nelson, RAC
Director of Regulatory/Quality Affairs
6045 Cochran Rd.
Solon, OH 44139

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Re: K110429
Trade/Device Names: ProSim 4, 6 and 8
Regulatory Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including Cardiotachometer and Rate Alarm)
Regulatory Class: Class II (Two)
Product Code: DRT
Dated: August 26, 2011
Received: August 29, 2011

Dear Mr. Nelson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

FLUKE.
Biomedical

Indications for Use

ProSim 4

510(k) Number (if known): K110429

Device Name: ProSim4

Indications for Use:

The ProSim 4 Vital Signs Simulator provides electronic and pneumatic simulation of physiological parameters for determining that patient monitoring devices or systems are performing within their operating specifications. The device includes the following physiological simulations:

- ECG – adult or neonatal
- Invasive and non-invasive blood pressure
- Respiration

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____X___ (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K110429

FLUKE.
Biomedical

Indications for Use

ProSim 6/8

510(k) Number (if known): K110429

Device Name: ProSim6/8

Indications for Use:

The ProSim 6 and ProSim 8 Vital Signs Simulators provide electronic and pneumatic simulation of physiological parameters for determining that patient monitoring devices or systems are performing within their operating specifications. The devices provide the following physiological simulations:

- ECG – adult or pediatric
- Invasive and non-invasive blood pressure
- Respiration
- Temperature
- Cardiac Output
- Fetal Simulation – includes fetal, maternal ECG, & uterine contractions (ProSim 8 only)

Additionally, the devices provide an optical signal to verify that the electronics within the pulse oximeter probe are functional

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __X_____ (21 CFR 807 Subpart C)

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